

*Please note:*

*These draft proposals for revising certain sections in the current ELAP regulations were submitted to ELAP by a sub committee of the Environmental Laboratory Technical Advisory Committee. The proposals affect Definitions (Section 64801), Performance Evaluation Testing (Section 64809), and Subgroups for Fields of Testing (Section 64823).*

*These proposals have not yet been reviewed or evaluated by ELAP or the Department of Health Services, and do not necessarily represent the views or opinions of ELAP/ DHS.*

*Anyone wishing to comment on these proposals should submit their comments by June 30, 2003 to George Kulasingam, Ph.D., ELAP, 1625 Shattuck Ave, Room 101, Berkeley, CA 94709-1611. Any comments received will also be passed on to the sub committee which originated these proposals.*

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## Article 5 Proficiency Testing (PT) Evaluation Process.

### **Section 64809.**

- a) Each laboratory certified or applying for initial certification, amendment of certification, reinstatement, and/or renewal under the Environmental Laboratory Accreditation program (ELAP) for a field-of-testing (FOT) specified in Section 64823 shall participate in proficiency testing studies, as described in Section 64809 and analyze proficiency testing study samples in the matrix representative of the field-of-testing in which the laboratory is certified or requesting certification.
- b) A laboratory shall be accredited to perform analyses in any combination of matrix-method-analyte in any Field(s) of Testing as identified in Section 64823 after the laboratory has submitted acceptable results for the analysis of proficiency testing (PT) sample(s). Laboratories shall obtain PT samples from PT providers that are accredited by NIST/NVLAP or A2LA to the requirements contained in the USEPA Criteria Document and NELAC Chapter 2 Standards for the specific combinations of matrix-method-analyte for which both the provider and the laboratory are accredited. On an annual basis, ELAP will update a list of accredited PT providers and make this list available to all accredited laboratories.
- c) No laboratory shall be certified to perform combinations of matrix–method–analyte of any Field(s) of Testing as identified in Section 64823 unless the laboratory has submitted results for the analysis of PT samples or sets (where PT sample study sets exist) in each combination of matrix–method–analyte

within each Field of Testing for which certification is requested, and the results are in agreement with the criteria established below. If PT samples are not available from any accredited Provider, then the Laboratory is not held accountable for compliance with this section unless the Department provides samples. Whether the PT sample(s) comes from an accredited Provider or the Department, the PT sample design and acceptance criteria cited below shall apply.

- d) Laboratories accredited by ELAP for either drinking water, wastewater or hazardous waste shall participate in proficiency testing studies that comply with all requirements contained in the USEPA Criteria Document and NELAC Chapter 2 Standards, except as related to the required PT study frequency and schedule requirements, which are defined herein. Participation in PT studies that do not meet these requirements or submittal of study results after the NELAC required study closure date shall be deemed a failed performance in said study.
- e) The PT samples must be designed and the PT results evaluated by the following requirements and criteria:
  - 1) Where the PT sample design and acceptance criteria for any combination of matrix-method-analyte are cited in either the United States Code of Federal Regulation Title 40 Section 141 or the USEPA Criteria Document, these requirements and acceptance criteria must be followed. In the event of a conflict between the requirements and criteria contained in 40 CFR 141 and the USEPA Criteria Document, the former shall take precedence.
  - 2) Where ELAP accredits any combination of matrix-method-analyte and PT sample requirements and PT acceptance criteria do not exist in either 40 CFR 141 or the USEPA Criteria Document, the sample design requirements and PT acceptance limits found in the currently applicable NELAC Chapter 2 Standards and its appendices shall be followed.
  - 3) Where ELAP accredits any combination of matrix-method-analyte and USEPA and NELAC Chapter 2 PT acceptance criteria do not exist, concentration ranges and acceptance criteria shall be set by an expert panel convened by the Division of Laboratory Sciences.
    - a. The expert panel shall be convened each January and shall serve for the calendar year. The panel shall consist of nine individuals, three from accredited laboratories selected by the Environmental Laboratory Technical Advisory Committee (ELTAC), three from recognized manufacturers of PT samples selected by the Division of Laboratory Sciences, and one member each from DDWEM, SWRCB, and DTSC. The panel may consult all individuals or organizations that it deems appropriate and will consider unsolicited comments. There will be one ex officio non-voting member from ELAP staff.

- b. The panel shall use established statistical techniques & regulatory needs to determine PT acceptance criteria.
- c. If the panel wishes to make changes to the PT criteria for the following calendar year, they must complete a report by September 30. The report must be posted on the ELAP homepage by that date and made available for public comment. The report is subject to approval by the Program Chief for ELAP prior to posting for public comment. If the Program Chief does not approve the report, it will be returned to the panel with instructions for revision and resubmittal. The report must explain how each criterion was set, including data sets and criteria setting procedures.
- d. There must be a public meeting no later than October 31 in order to take public input on specific criteria or criteria setting methods.
- e. In order for criteria to be implemented for a calendar year, the final ELAP report shall be finalized and posted no later than November 30.

Submission of results from PT samples prepared or scored using other criteria shall constitute an “unacceptable” result.

- f) Specific requirements for the frequency and timing of participation in proficiency testing studies described in this and following sections will take precedence over the requirements contained in the NELAC Chapter 2 Standards.. Annually a laboratory must successfully analyze a PT sample for each combination of matrix, method and analyte included in the laboratory’s Scope of Accreditation, where available. A laboratory applying for initial accreditation must submit evidence to ELAP of a successfully completed PT study. Laboratories may not begin participation in a PT study prior to January 1 and all studies must close by December 31.
- g) Laboratories accredited in Field of Testing 114, 115, 116, 117, 118, 119, or 120 that analyze only aqueous liquids may satisfy the PT requirement by analyzing a liquid PT sample such as a Water Pollution (WP) sample. Laboratories accredited for Field of Testing 114, 115, 116, 117, 118, 119, or 120 that also analyze solids and/or non-aqueous liquids must analyze a solid phase PT sample to satisfy the annual PT requirement.
- h) For any combination of matrix-method-analyte that the laboratory does not receive a score of “Acceptable” in the PT study, the laboratory may request that it be given a second attempt to submit such results. Prior to participating in the second PT study, the laboratory must take Corrective Action(s), maintain records of such actions, and submit a corrective action summary for each failed analyte to the Department within 30 days of receipt of the evaluation report from the Provider of the proficiency testing study. The corrective action summary shall include the laboratory’s determination of the cause(s) for each “not acceptable” evaluation, and actions taken to improve future data quality.

- i) Laboratories shall be limited to two PT sample studies per calendar year, per combination of matrix, method and analyte, except those accredited under FOTs 123, 124, 125, or 126.
- j) In the event that laboratory fails two PT samples in a calendar year, ELAP shall have the authority to begin legal action to suspend or revoke the laboratory's existing accreditation for that matrix, method and analyte that the laboratory failed. ELAP shall notify the laboratory in writing that it intends to revoke accreditation. If the laboratory agrees, ELAP shall issue a new certificate to the laboratory reflecting the change in accreditation. Otherwise, the laboratory shall have a hearing in accordance with the California Administrative Code.
- k) A laboratory that has lost accreditation for a given matrix-method-analyte may apply for new accreditation in the same fashion as initial accreditation as described in Article 2. However, the laboratory must successfully pass two PT samples for the matrix, method and analyte analyzed not less than 30 days apart.
- l) Failure of a laboratory accredited to the ELAP California state specific criteria to submit results for the analysis of PT sample meeting the requirements of Section 64809 by December 31 may be a condition for the Department to begin legal action to revoke accreditation for those analytes.

Reference: Sections, 100860.1 and 100872(a) Health and Safety Code.